Inventiva receives another positive opinion on orphan drug designation in the European Union for IVA337 – for Idiopathic Pulmonary Fibrosis

This follows an earlier positive opinion for IVA337 in October regarding the treatment of Systemic Sclerosis (SSc)

Dijon, France, December 2, 2014 - Inventiva, a drug discovery company that focuses on therapeutic approaches involving transcription factors and epigenetic targets, today announces that the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA) has given a positive opinion on the designation of IVA337 as an orphan medicinal product for the treatment of Idiopathic Pulmonary Fibrosis (IPF).

”After Systemic Sclerosis, Idiopathic Pulmonary Fibrosis is the second indication for which EMA granted IVA337 a positive opinion on orphan drug designation. It clearly indicates the potential our product IVA337 could have to treat fibrosis in various organs,” said Frédéric Cren, CEO and co-founder of Inventiva.

IPF is a chronic, progressive and fatal lung disease with no known cause. It is characterised by progressive dyspnoea and irreversible loss of lung function. The clinical course of the disease is variable and unpredictable with a uniformly poor prognosis.

“The medical need in IPF is tremendous and we believe IVA337 offers additional benefits when compared to current treatments. It has real potential,” said Pierre Broqua, chief scientific officer and co-founder of Inventiva. “Our clinical candidate mechanism of action clearly acts on various fibrotic pathways to deliver a unique therapeutic approach. The studies we have already performed with IVA337 in other indications allow us to quickly envisage a proof of concept study in IPF.”

IVA337 is a patent protected NCE (New Chemical Entity) that has previously demonstrated good tolerability, safety and efficacy in phase I and II studies in an unrelated indication. IVA337 has been investigated in several preclinical models of fibrotic disorders (lung, skin and liver).

In October 2014 IVA337 received a positive opinion on orphan drug designation as a treatment for Systemic Sclerosis (SSc). Inventiva is currently planning to start a phase IIa SSc clinical study in 2015.

About IPF

IPF is associated with a number of co-morbidities, including pulmonary hypertension, COPD, lung cancer, coronary artery disease, diastolic dysfunction, gastro-oesophageal reflux disease, sleep disorders and psychiatric disturbances. The ultimate pattern is deterioration, with an estimated median survival of 2-3 years. The estimated prevalence in Europe is not more than 3 patients per 10,000.

About orphan drug designation

Orphan drug designation by the European Commission provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union (EU) and where no satisfactory treatment is available.

In addition to a 10-year period of marketing exclusivity in the EU after product approval, orphan drug designation provides incentives for companies seeking protocol assistance from the EMA during the product development phase and direct access to centralized marketing authorization.

About Inventiva

Inventiva is a drug discovery company that focuses on therapeutic approaches involving transcription factors and epigenetic targets (particularly the HKMT family) to discover innovative treatments for cancer, fibrosis, immuno-inflammatory diseases and Parkinson's disease.

The company's business strategy is to engage in proprietary research programs and secure drug discovery partnerships with pharmaceutical groups. It also offers a full range of research services. These draw on its extensive technology platform, a proprietary library of 240,000 compounds and a fibrosis platform. Inventiva also has expertise in nuclear receptors, transcription factors and epigenetic modulation. Over 100 employees are based at its research center in Daix, near Dijon (France).

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